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Cost-effectiveness of culture-guided antimicrobial prophylaxis for the prevention of infections after prostate biopsy

Chi-kong Li, Brian C.Y. Tong, Joyce H.S. You *

School of Pharmacy, Faculty of Medicine, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong, China

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SUMMARY

Background: Clinical findings suggest that the use of rectal culture-guided antibiotic prophylaxis reduces the infection rate following transrectal ultrasound-guided prostate biopsy (TRUSBx).
Methods: A decision-analytic model was designed to compare the outcomes of TRUSBx performed with (rectal culture-guided group) and without (standard ciprofloxacin prophylaxis) rectal swab culture-guided antimicrobial prophylaxis in Hong Kong. The post-biopsy infection rate, infection-related costs, quality-adjusted life years (QALYs) lost for infection, and incremental cost per QALY saved (ICER) were assessed. Model inputs were retrieved from local epidemiology data and the medical literature. A sensitivity analysis was performed to test the robustness of the model results.
Results: Base-case analysis showed that the infection rate in the culture-guided group was reduced from 2.42% to 0.23% and saved 0.0002 QALYs, with a lower cost (USD 31.4 versus USD 55.6) (USD 1 = HKD 7.8). The number needed to screen to prevent an infection episode was 45.7. The hospital days avoided per 100 patients using culture-guided prophylaxis was 7.08 days. The relative effectiveness of culture-guided antimicrobial prophylaxis versus standard prophylaxis in carriers and non-carriers of FQ-resistant rectal flora were identified as potential influencing factors. In 10 000 Monte Carlo simulations, ICERs of the culture-guided group were below the willingness-to-pay threshold 99.12% of the time.
Conclusions: Using rectal culture-guided antimicrobial prophylaxis for men undergoing TRUSBx appears to be a cost-saving strategy to avert post-biopsy infection and QALY loss in Hong Kong.

1. Introduction

Despite the lower incidence of prostate cancer in Asian regions than in Western nations, the Hong Kong Cancer Registry has reported prostate cancer to be the third most common cancer in men.[1,2] Transrectal ultrasound-guided prostate biopsy (TRUSBx) is a commonly performed procedure for the diagnosis of prostate cancer, and infection (including urinary tract infection, prostatitis, and sepsis) is a well-established complication of this procedure. The rate of infection post-TRUSBx ranges from 0.5% to 6.6%, with hospitalization rates between 0.5% and 4.8%.[3]

Fluoroquinolones (FQs) are frequently used for periprocedure antimicrobial prophylaxis,[4] yet the emerging prevalence of FQ-resistant bacteria in faecal carriage of patients undergoing TRUSBx has increased the risk of post-biopsy infection.[5] Pre-biopsy rectal swab culture is therefore suggested to identify the resistance of the rectal flora prior to selecting antimicrobial prophylaxis. The findings of clinical trials strongly suggest that antimicrobial prophylaxis be directed by rectal culture to reduce the odds of infection, with the possibility of eliminating post-biopsy infection.[6,7]

With the initiatives of the Department of Health to enhance public awareness of prostate cancer screening, the number of males undergoing TRUSBx is anticipated to increase in Hong Kong.[8] A recent study reported a high prevalence of FQ-resistant rectal flora (40.4%) in Hong Kong males undergoing TRUSBx, suggesting that a targeted approach to antimicrobial prophylaxis using rectal culture is warranted.[9] A cost-effectiveness analysis is essential to facilitate the decision-making process with regard to implementing pre-TRUSBx rectal culture swab to guide the selection of prophylactic agent. The objective of this study was to examine the potential costs, post-biopsy infection rate, and health-related quality of life of men undergoing TRUSBx with or without periprocedure rectal swab culture, from the societal perspective of Hong Kong.

* Corresponding author. Tel.: +852-3943-6830; fax: +852-2603-5295.
E-mail address: joyceyou@cuhk.edu.hk (Joyce H.S. You).

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2. Methods

2.1. Model design

A decision-analytic model (Figure 1) was designed to compare the economic and clinical outcomes of TRUSBx performed with (rectal culture-guided group) and without (standard group) rectal swab culture-guided antimicrobial prophylaxis. The outcomes simulated in the present model included the post-biopsy infection rate, infection-related direct medical cost and indirect cost, and quality-adjusted life years (QALYs) lost for post-biopsy infection. A hypothetical cohort of male subjects aged 55 years and above (newly diagnosed cases of prostate cancer in Hong Kong have mainly fallen into this age group[10]) undergoing TRUSBx were included in this model. Exclusion criteria included allergy to FQ.

Rectal swabs would be collected for subjects in the culture-guided group within 1 month prior to TRUSBx.[6,7] The choice of culture-specific regimen included sulfamethoxazole–trimethoprim, cefuroxime, or cefazolin monotherapy and the combination of ciprofloxacin and gentamicin.[6,7,11,12] Subjects in the standard group would receive oral ciprofloxacin before TRUSBx.[5,6,13–15] A post-biopsy infection might occur in any patient in both study arms; those who were infected might be managed in the outpatient setting or be hospitalized. Post-biopsy infections were defined clinically, including urinary tract infection and bloodstream infection.[6,7] No mortality as a result of post-TRUSBx infectious complications was reported in the local epidemiology study,[9] and the present model therefore assumed no post-biopsy infection-related deaths.

2.2. Clinical inputs

A literature search of MEDLINE for the period 2000 to 2015 was performed using the following key terms: "prostate biopsy", "fluoroquinolone resistance", "rectal flora", "antimicrobial prophylaxis", "urinary tract infection", and "bacteremia". The selection criteria for the clinical trials were: (1) report written in the English language; (2) prevalence of FQ-resistant rectal flora was reported, and/or (3) the post-biopsy infection rate was reported. All articles retrieved by this process were screened for relevance to the model. For a variable that was reported in multiple studies, the weighted average was used to estimate the base-case value.

The clinical inputs are shown in Table 1. The base-case values of the following clinical inputs were estimated from an epidemiological study performed in Hong Kong Chinese men undergoing TRUSBx:[9] prevalence of FQ-resistant rectal flora and post-biopsy infection rates in carriers and non-carriers of FQ-resistant rectal flora in the standard group. The prevalence of FQ-resistant rectal flora (40.4%) reported in Hong Kong was found to be much higher than those reported in other regions (10.8–19.6%).[11,16–18] The variation in prevalence of FQ resistance was therefore examined over a range of 10.8–40.4%. The base-case values of relative effectiveness of culture-targeted (versus standard) prophylaxis in carriers (100%) and non-carriers (79%) of FQ-resistant rectal flora were estimated from a clinical trial comparing the post-biopsy infection rate before and after the implementation of pre-procedure rectal culture.[7] A broad range (34–100%), with the lower limit value (34%) reported in a case–control study,[6] was examined in the sensitivity analysis for these two variables. The post-biopsy infection rate with culture-guided prophylaxis was calculated using the following equation: infection rate with standard ciprofloxacin prophylaxis × (1 − relative effectiveness of culture-guided prophylaxis).

The hospitalization rate of post-biopsy infection and length of hospital stay were retrieved from outcome studies on post-biopsy infectious complications of TRUSBx.[13–15,19] For infected patients who were managed exclusively in the outpatient setting, the number of outpatient visits was assumed to be 2 (range 1–3), including the first visit for symptom onset and diagnosis and the second visit for follow-up.

2.3. Cost inputs

The cost analysis of the present study was performed from the societal perspective of Hong Kong and included the direct medical cost (costs of rectal swab culture, standard and culture-guided prophylactic regimens, and inpatient and outpatient care for post-biopsy infection) and the indirect cost (loss of productivity during post-biopsy infection).

The standard prophylactic regimen for TRUSBx in Hong Kong was single-dose ciprofloxacin 500 mg taken perioperatively,[9] and the empirical ciprofloxacin regimen varied from a single dose to 6 doses (3 days).[5–7,13–15] Culture-guided regimens included monotherapy of sulfamethoxazole–trimethoprim, cefuroxime, or cefazolin,[7,17] and the combination of ciprofloxacin and gentamicin.[6,12] The costs of antibiotic prophylaxis were calculated from the unit cost of antibiotic(s) and the quantity taken.

The cost of infection for patients who were managed exclusively in the outpatient setting was estimated from the number of outpatient visits and cost per outpatient visit. The cost of infection for patients who were hospitalized included both inpatient and outpatient care. The cost of inpatient care was calculated from the length of stay and daily cost of hospitalization on the general medical ward. The model inputs for cost per outpatient visit and daily cost of the general medical ward were estimated from charges to non-residents of the Hospital Authority.[20] The Hospital Authority is the largest public healthcare provider for Hong Kong residents. It is non-profit making and is subsidized by the government, and the charges to non-residents were therefore assumed to represent solely the cost of the healthcare services without profit.

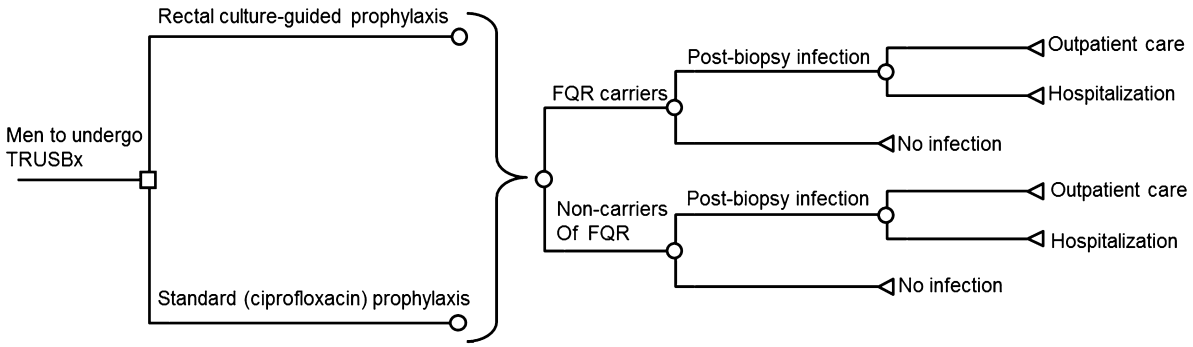

Figure 1. Simplified decision-analytic model (TRUSBx, transrectal ultrasound-guided prostate biopsy; FQR, fluoroquinolone resistance).

Table 1
Model inputs

	Base-case value	Range for sensitivity analysis	Reference
Clinical inputs			
Prevalence of FQ-resistant rectal flora	40.4%	10.8–40.4%	9, 11, 16–18
Rate of post-biopsy infection in standard prophylaxis group			7, 9
Carriers of FQ-resistant rectal flora	3.33%	3.33–42.9%	
Non-carriers of FQ-resistant rectal flora	1.81%	1.81–2.70%	
Relative effectiveness of rectal culture-targeted (versus standard) prophylaxis in:			6, 7
Carriers of FQ-resistant rectal flora	100%	34–100%	
Non-carriers of FQ-resistant rectal flora	79.3%	34–100%	
Rate of hospitalization for post-biopsy infection	64.6%	51.4–77.5%	13–15
Length of hospital stay for post-biopsy infection	5	3–7	19
Total length of antibiotic treatment for post-biopsy infection	21	14–28	19
Number of clinic visits for outpatient treatment of post-biopsy infection	2	1–3	Assumption
Utility inputs			
Disutility of post-biopsy infection managed in the outpatient setting	−0.14	−0.168 to −0.112	22
Increment factor of disutility of post-biopsy infection in the hospital versus outpatient setting	2	1.5–3	Assumption
Cost inputs (USD)[a]			
Rectal swab	25	18–30	Local
Cost of standard antimicrobial prophylaxis[b]	0.72	0.06–0.72	Local
Cost of culture-guided antimicrobial prophylaxis[c]	1.15	0.4–6.0	Local
Cost of outpatient visit for post-biopsy infection (per visit)	50	49–127	20
Cost of hospitalization for post-biopsy infection (per day)	600	480–720	20
Average salary of population aged 55 years or older (per day)	50	40–60	21

FQ, fluoroquinolone; TRUSBx, transrectal ultrasound-guided prostate biopsy.
[a] USD 1 = HKD 7.8.
[b] The standard prophylactic regimen for TRUSBx in Hong Kong was single-dose ciprofloxacin 500 mg (base-case) and varied from a single dose to 6 doses (3 days).
[c] Culture-guided regimens included monotherapy with sulfamethoxazole–trimethoprim, cefuroxime, or cefazolin, and the combination of ciprofloxacin and gentamicin.

The loss of productivity of patients due to post-biopsy infection was estimated from the median daily income (non-sex-specific) of the Hong Kong population aged 55 years and above[21] and the length of hospitalization (for hospitalized cases only) and the number of days attending the outpatient clinic (for all infected patients).

2.4. Utility inputs

The loss of QALYs associated with post-biopsy infection was examined. An outcome study of Chinese outpatients with prostatitis reported a disutility of −0.14 compared to the utility of the general population.[22] The disutility of post-biopsy infection managed in the hospital setting was assumed to be 2-fold (range 1–3-fold) the disutility of outpatient care. The QALY loss of patients who received only outpatient care for infection was estimated from the disutility of outpatient care and the length of antimicrobial treatment. The duration of the antimicrobial treatment course was retrieved from an epidemiological study on prostatitis.[18] The QALY loss for hospitalized patients was estimated from the disutility of hospitalization and length of hospital stay and from the disutility of outpatient care and remaining duration of antimicrobial therapy (remaining days of treatment = length of treatment − length of hospital stay).

2.5. Cost-effective analysis and sensitivity analysis

The culture-guided group would dominate the standard group if it cost less and resulted in QALYs saved. If the culture-guided group cost more to save QALYs, the incremental cost per QALY saved (ICER) was calculated using the following equation: $(\text{Cost}_{\text{culture-guided}} - \text{Cost}_{\text{standard}})/(\text{QALY loss}_{\text{standard}} - \text{QALY loss}_{\text{culture-guided}})$. As recommended by the World Health Organization (WHO), an ICER less than 1× GDP per capita was considered as highly cost-effective.[23] The GDP per capita of Hong Kong in 2014 was USD 39 758 and the scenario of an ICER less than USD 39 758 was considered as the preferred option.[24]

The sensitivity analysis was performed using TreeAge Pro 2009 (TreeAge Software, Inc., Williamstown, MA, USA) and Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA) to examine the robustness of the model results. All of the parameters were examined over the upper and lower limits of the variables, if available. Otherwise, a range of variation of ±20% of the base-case value was used. A one-way sensitivity analysis on all model inputs was performed to screen for potential influencing factors. To evaluate the impact of uncertainty in all variables simultaneously, a probabilistic sensitivity analysis was performed using Monte Carlo simulation. The total cost and QALYs of each study arm were recalculated 10 000 times by randomly drawing each of the model inputs from a triangular probability distribution to determine the percentage of time in which each strategy would be the preferred option.

3. Results

3.1. Base-case analysis

In the base-case analysis (Table 2), the culture-guided group showed a reduction in the post-biopsy infection rate of 90.5% (from 2.42% to 0.23%); 0.0002 QALYs per patient were saved. The number needed to screen to prevent an infection was 45.7. In comparison with the standard group, the culture-guided group reduced the total cost per patient undergoing biopsy by 43.5% (USD 31.4 versus

Table 2
Base-case analysis of expected costs, post-biopsy infection rate, and QALYs lost per subject undergoing transrectal ultrasound-guided prostate biopsy[a]

	Culture-guided prophylaxis group	Standard prophylaxis group
Total cost per patient (USD)	$31.4	$55.6
Direct cost (USD)	$30.8	$49.3
Indirect cost (USD)	$0.6	$6.3
Post-biopsy infection rate per 100 patients	0.23	2.42
Hospital days per 100 patients	0.74	7.82
QALY loss per patient	0.00002	0.00023

QALY, quality-adjusted life-year.
[a] USD 1 = HKD 7.8.

USD 55.6; USD 1 = HKD 7.8) from the societal perspective, and reduced the direct cost by 37.5% (USD 30.8 versus USD 49.3) from the healthcare payer's perspective. The hospital days avoided per 100 patients by culture-guided prophylaxis was 7.08 days. The culture-guided group showed a reduced infection rate with cost saving and lower QALY loss, and therefore dominated the standard group in the base-case scenario.

3.2. Sensitivity analysis

The one-way sensitivity analysis found the base-case results to be robust throughout variation of all model inputs. The relative effectiveness of culture-guided antimicrobial prophylaxis versus standard prophylaxis in carriers and non-carriers of FQ-resistant rectal flora were identified as potential influencing factors. These two inputs were examined further over an extended range (0.1–100%) at three prevalence levels of FQ-resistant rectal flora (10%, 25%, and 40%) by three-way sensitivity analysis (Figure 2). The number of variable combinations preferring the culture-guided group (as indicated by the size of the grey area in Figure 2) increased from a low level prevalence of FQ resistance to a high level of FQ resistance. At a low prevalence of FQ resistance (10% and 25%), the relative effectiveness of culture-guided prophylaxis in non-carriers of FQ-resistant rectal floral was the prominent influencing factor, and thresholds of >40% (at 10% of FQ-resistance) and >10% (at 25% of FQ-resistance) were identified for the culture-guided group to be cost-effective. At a high prevalence of FQ resistance (40%), a threshold value of 72.6% for relative effectiveness of culture-guided prophylaxis in carriers was identified when the relative effectiveness in non-carriers was at the lower limit (0.1%). To examine the impact of high antimicrobial regimen cost in the present model analysis, the cost range of culture-specific antimicrobial prophylaxis was extended from USD 0.4–6 to USD 0.4–50 in a one-way sensitivity analysis; the culture-guided group remained cost-saving if the prophylactic regimen cost less than USD 25.6.

The probabilistic sensitivity analysis was performed by 10 000 Monte Carlo simulations. The culture-guided group was significantly less costly and more effective than the standard group, with a mean cost saving of USD 17.9 (95% confidence interval (CI) 17.7–18.1; $p < 0.001$) and 0.000180 QALY saved (95% CI 0.000179–0.000181; $p < 0.001$). A scatter plot showing the incremental cost versus QALY saved by culture-guided group is given in Figure 3. The culture-guided group reduced the cost and saved QALYs in 96.03% of the simulations, and it cost more to save QALYs in 3.97% of the simulations. The ICERs per QALY saved by the culture-guided group were below the willingness-to-pay threshold in 99.12% of the simulations. The acceptability of culture-guided prophylaxis as the preferred option changed from 96.0% to 99.5% when the willingness-to-pay threshold increased from USD 0 to USD 50 000, respectively.

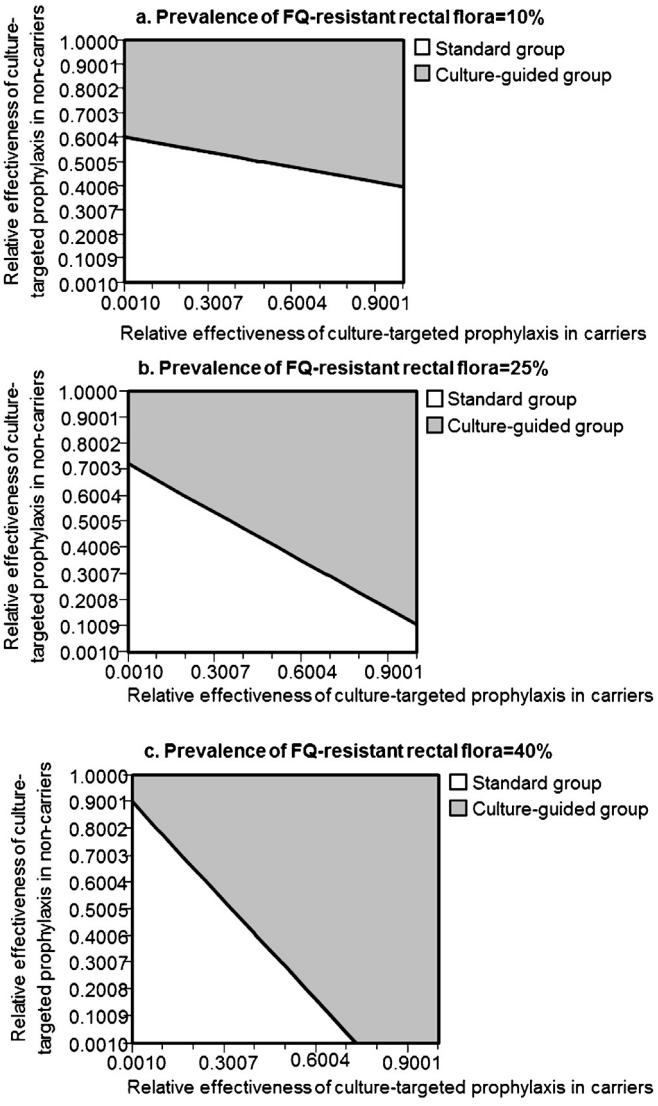

Figure 2. Three-way sensitivity analysis of relative effectiveness of culture-guided versus standard prophylaxis in carriers and in non-carriers of fluoroquinolone (FQ)-resistant rectal flora on increment cost per QALY saved (ICER) at various prevalence levels of FQ-resistant rectal flora: (a) 10%, (b) 25%, (c) 40%. The threshold line divides the grey zone and white zone. Combinations of variables on the threshold line had the same cost-effectiveness for both study arms. Grey zone: combinations of variables leading to ICERs in the culture-guided group of less than the willingness-to-pay threshold (USD 39 758) (preferred option = culture-guided group). White zone: combinations of variables leading to ICERs in the culture-guided group greater than the willingness-to-pay threshold (USD 39 758) (preferred option = standard group).

4. Discussion

The base-case results of the present study found rectal culture-guided prophylaxis to be cost-saving and to gain QALYs when compared with standard prophylaxis in patients undergoing TRUSBx from the societal perspective of Hong Kong. Culture-guided prophylaxis reduced the total cost (per man undergoing TRUSBx) by over 40% (from USD 55.6 to USD 31.4), including the direct medical costs for the prevention and treatment of infection

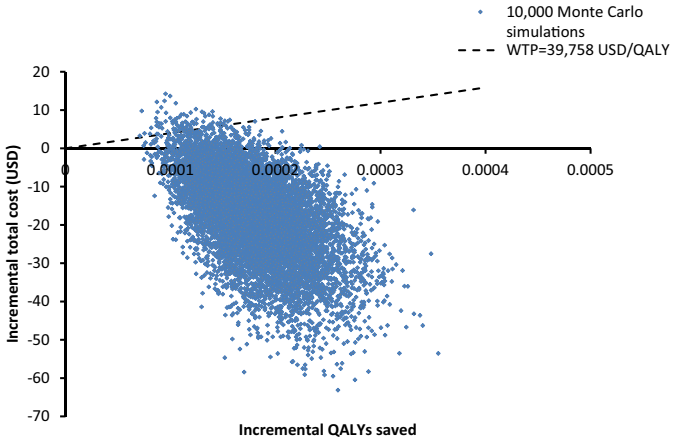

Figure 3. Scatter plot of incremental cost versus incremental QALYs saved by culture-guided prophylaxis versus standard prophylaxis.

by over 37% (from USD 49.3 to USD 30.8) and the loss of productivity for post-biopsy infection (indirect cost) by over 90% (from USD 6.3 to USD 0.6). The infection rate was reduced by over 90% (from 2.42% to 0.23%). The robustness of the base-case analysis findings was demonstrated in both the one-way sensitivity analysis (no threshold value for all model inputs) and the probabilistic sensitivity analysis (culture-guided group was the preferred option in over 99% of 10 000 Monte Carlo simulations).

The one-way sensitivity analysis found two variables (relative effectiveness of culture-guided prophylaxis versus standard prophylaxis in FQ-resistant flora carriers and non-carriers) to influence the ICER of the culture-guided group, despite no threshold value being identified. The interactions of varying these two model inputs over three prevalence levels of FQ resistance in a three-way sensitivity analysis showed that the relative effectiveness of culture-guided prophylaxis in carriers was most influential in scenarios with a high prevalence of FQ-resistant rectal flora, when compared to those with a low prevalence.

In a prospective cohort study (n = 457) conducted in the USA, Taylor et al. reported that there was no infectious complication in 112 men who received culture-guided antimicrobial prophylaxis, whereas infectious complications occurred in nine of 345 (2.6%) men on standard prophylaxis. The cost analysis of this cohort study demonstrated a cost-saving of USD 4499 per post-biopsy infection averted with a number needed to screen of 38.[11] The present analysis found culture-guided prophylaxis to be cost-saving per infection avoided (USD 1,105) and the number needed to screen to prevent one infectious complication was found to be 45.7. These results are similar to the cost-effectiveness findings reported by Taylor et al., despite higher cost-savings demonstrated in the US study. The difference was mainly due to the low healthcare service unit cost and drug costs in Hong Kong (Table 1) compared to the US Medicare reimbursement rate for infection.[11] For every case of infection averted, a relatively lower direct cost of treatment was saved in Hong Kong compared to the USA because of the lower cost of care in Hong Kong.

A cost-effectiveness analysis comparing standard versus intensive antibiotic prophylaxis for TRUSBx reported by Adibi et al. using decision tree analysis from the perspective of US healthcare providers, showed standard prophylaxis (drug cost USD 1) to be less costly than an intensive antibiotic regimen (drug cost USD 33), but this resulted in a higher post-biopsy infection rate.[25] The present sensitivity analysis further identified the threshold of culture-targeted antimicrobial drug cost to be US 25.6 or less for pre-biopsy rectal culture screening to remain cost-saving. Compared to empirical broad-spectrum antibiotic prophylaxis, culture-guided prophylaxis could reduce the drug costs without compromising the effectiveness in infection prevention.

This is the first cost-effectiveness analysis conducted from the societal perspective of Hong Kong to include direct medical costs and indirect costs, as well as the post-biopsy infection rate and QALY loss of patients undergoing TRUSBx with and without pre-biopsy rectal swab culture. The present study identified influencing factors and corresponding threshold values (high versus low prevalence of FQ-resistant rectal flora, relative effectiveness of culture-guided prophylaxis in carriers and non-carriers of FQ-resistant rectal flora), which may serve as reference values to assist clinicians and administrators in deciding the prophylaxis protocol for TRUSBx. The base-case results supported rectal culture-guided prophylaxis in a city with a high prevalence of FQ resistance (40%), and the findings were further shown to be robust and generalizable to low prevalence (10%) regions in the sensitivity analysis. The present model framework, including key clinical and cost parameters, allowed the incorporation of different antimicrobial regimens using agent-specific costs, the region- or institution-specific prevalence of FQ-resistance, and agent-specific effectiveness for the prevention of post-biopsy infection to better reflect the costs and clinical outcomes of different practice settings.

A high prevalence of FQ-resistant rectal flora has been reported in Chinese men undergoing TRUSBx in Hong Kong. Despite the post-biopsy infection rate using standard prophylaxis with oral ciprofloxacin remaining low (2.4%) in Hong Kong,[9] findings in recent cohort trials have demonstrated the possibility of eliminating post-biopsy infection with culture-guided prophylaxis.[7,11,18] The results of the present study further support the economic and clinical benefits of a rectal culture-guided prophylaxis protocol for TRUSBx.

The present study was limited by the sources of clinical effectiveness of culture-guided prophylaxis, mostly estimated from cohort studies. The clinical inputs were therefore examined over a wide range in the sensitivity analysis to examine their influence on the robustness of model results. This model simplified the outcomes of post-biopsy infection and did not differentiate the severity of infectious complications between patients infected with drug-resistant versus susceptible pathogens. Thus the clinical benefits of culture-guided prophylaxis might be underestimated. The estimation of productivity loss did not include the indirect cost of caregivers and might have undermined the cost-savings of culture-guided prophylaxis.

In conclusion, rectal culture-guided antimicrobial prophylaxis for men undergoing TRUSBx appears to be a cost-saving strategy compared to standard ciprofloxacin prophylaxis to avert post-biopsy infection and infection-associated QALY loss, from the societal perspective of Hong Kong.

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Conflict of interest: None.

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